TITLE 11

ADMINISTRATIVE RULES

STATE DEPARTMENT OF HEALTH

CHAPTER 113

SUBSTANCE ABUSE TESTING

DEPARTMENT OF HEALTH

Adoption of Chapter 11-113
Hawaii Administrative Rules

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Chapter 113 of Title 11, Hawaii Administrative Rules, entitled "Substance Abuse Testing," is adopted.

HAWAII ADMINISTRATIVE RULES

TITLE 11

DEPARTMENT OF HEALTH

CHAPTER 113

SUBSTANCE ABUSE TESTING

§11-113-1 Purpose. The purpose of this chapter is to ensure that appropriate and uniform substance abuse test procedures are employed throughout the State, to protect the privacy rights of persons tested, and to achieve reliable and accurate results.
[Eff JAN 23 1992] (Auth: HRS §§329B-1, 329B-8)
(Imp: HRS §329B-1)

§11-113-2 Definitions. As used in this chapter:
"Alcohol" means ethyl alcohol.
"Chain of custody" means procedures to account for the integrity of each specimen by tracking its handling and storage from point of specimen collection to final disposition of the specimen.
"Collection site" means a place where the individual presents himself or herself for the purpose of providing a urine or blood specimen for substance abuse testing.
"Collection site person" means a person who instructs and assists individuals at a collection site and who receives and makes an initial examination of the urine specimens provided by those individuals.
"Collector of blood specimens" means a person who collects a blood specimen pursuant to section 11-113-7.
"Confirmatory test" means a controlled substance or alcohol test that uses a method of analysis determined by the director of health to be reliable in establishing the identity and quantity of alcohol, drugs, or metabolites of drugs in the specimen.
"Cutoff level" means that concentration of a substance, established by the director, in a specimen below which dictates a negative result for that test.
"Department" means the department of health, State of Hawaii.
"Director" or "director of health" means the director of the department of health.
"Drug" means a controlled substance as defined in chapter 329, Hawaii Revised Statutes.
"False positive" means reporting the presence of a drug or its metabolite or alcohol which is not present at or above the cutoff level.
"Medical review officer" means an individual, licensed by the department, who has knowledge of

substance abuse disorders and toxicology as determined by the department, and is appointed by the third party to receive, review, and interpret the results of laboratory tests requested by the third party.

"Medication disclosure form" means a form approved by the director for the individual to be tested for the presence of drugs to voluntarily disclose any over-the-counter medication or prescribed drugs that the individual has taken within the previous thirty days.

"Negative specimen" means a specimen which was found to have negative test results for all substances for which the specimen was tested.

"Negative test result" means either a finding by testing of the absence of drugs, alcohol, or the metabolites of drugs, or their presence below the cutoff levels, in the specimen tested, or a positive test result which the medical review officer determines to be not attributable to substance abuse.

"ng/ml" means nanograms per milliliter of liquid specimen.

"Positive specimen" means a specimen which was found to have a positive test result.

"Positive test result" means a finding by confirmatory testing of the presence of drugs, alcohol, or the metabolites of drugs in the specimen tested in levels at or above the cutoff levels.

"Presumptive positive test result" means a finding, by a screening test, of the presence of drugs or the metabolites of drugs at or above the cutoff levels.

"Specimen" means urine, blood, or such other sample that the department determines to be appropriate for substance abuse testing.

"Screening test" means a laboratory test to eliminate negative specimens from further consideration.

"State" means State of Hawaii unless otherwise specified.

"Substance abuse test" means any testing procedure, excluding toxicology tests used in the direct clinical management of patients and tests for alcohol related to chapters 286 and 291, Hawaii Revised Statutes, designed to take and analyze body fluids or materials from the body for the purpose of measuring the amount of drugs, alcohol, or the metabolites of drugs in the specimen tested.

"Third party" means any person, agency, employer

or any other entity who requests substance abuse testing of another person or persons. Unless otherwise specified, "third party" shall include the party's designated staff.

"Verified positive test result" means a determination by the medical review officer that a positive test result for drugs, the metabolites of drugs, or alcohol can be attributed to substance abuse. [Eff JAN 23 1992] (Auth: HRS §§329B-2, 329B-8) (Imp: HRS §329B-2)

§11-113-3 Exemptions. Toxicology testing used in the direct clinical management of patients, testing for alcohol related to chapters 286 and 291, Hawaii Revised Statutes, testing pursuant to subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (53 FR 11986), and testing for third parties who are covered by any drug testing regulation promulgated by the Hawaii department of transportation or the U.S. Department of Transportation or any other federal agencies, are exempt from the provisions of this chapter. [Eff JAN 23 1992] (Auth: HRS §§329B-2, 329B-3, 329B-4, 329B-8) (Imp: HRS §§329B-2, 329B-3, 329B-4)

§11-113-4 Substances of abuse. Pursuant to this chapter, substances of abuse or their metabolites shall include:

(1) Marijuana
(2) Cocaine
(3) Amphetamines
(4) Opiates
(5) Phencyclidine
(6) Barbiturates
(7) Methaqualone
(8) Benzodiazepines
(9) Propoxyphene
(10) Methadone
(11) Alcohol; and
(12) Any other controlled substances in chapter 329, Hawaii Revised Statutes, and approved by the director. [Eff JAN 23 1992] (Auth: HRS §§329B-2, 329B-8) (Imp: HRS §329-2)

§11-113-5 Specimen collection. (a) Prior to

the collection of any sample for substance abuse testing, the individual to be tested shall be supplied by the third party with:

(1) A written statement of the specific substances to be tested for;

(2) A statement that over-the-counter medications or prescribed drugs may result in a positive test result; and

(3) A medication disclosure form.

(b) The individual shall be informed in writing that providing information on the medication disclosure form is optional and that the individual shall maintain custody of the form, provided that the individual may voluntarily disclose the information contained in the medication disclosure form to the medical review officer.

(c) The third party or laboratory shall provide one or more designated collection sites which have necessary personnel, materials, equipment, facilities, and supervision to provide the collection, security, temporary storage, and provisions for shipping or transportation of specimens to a substance abuse testing laboratory.

(d) Procedures of the third party or the laboratory shall provide for the designated collection site to be secure. If a facility cannot be dedicated solely to specimen collection, the portion of the facility being used for specimen collection shall be secure during the collection process.

(e) Chain of custody forms for specimens shall be properly executed by the collection site person or the collector of blood specimens authorized by the third party or the laboratory, upon receipt of specimens.

(f) No unauthorized personnel shall be permitted in any part of the designated collection site when specimens are collected.

(g) The collection site person or the collector of blood specimens shall not proceed with the collection without establishing the identity of the individual, such as with a photographic identification card or driver's license, or by verification of identity by the third party.

(h) If the individual fails to arrive at the assigned time, the collection site person or the collector of blood specimens shall contact the third party for instructions.

(i) Collection site personnel shall arrange to

have the collected specimens transported to the drug testing laboratory. The specimens shall be placed in containers designed to minimize the possibility of damage during shipment. The containers shall be securely sealed to eliminate the possibility of undetected tampering. On the tape sealing the container, the collection site person or the collector of blood specimens shall sign and enter the date specimens were sealed in the container for shipment. The chain of custody documentation shall be attached to each container sealed for shipment to the drug testing laboratory.

(j) A copy of that part of the permanent record book containing information about the samples shall be forwarded to the medical review officer.

(k) The permanent record book shall be the property of the third party, and the contents shall not be released to the testing laboratory.

(l) All information contained in the permanent record book and the chain of custody forms shall be kept confidential.

[Eff JAN 23 1992] (Auth: HRS §§329B-4, 329B-5, 329B-6, 329B-8) (Imp: HRS §§329B-4, 329B-5, 329B-6)

§11-113-6 Urine specimen. (a) In addition to section 11-115-5 of this chapter, the collection of urine specimens shall include the following:

(1) Procedures for collecting urine specimens shall allow for individual privacy unless there is reason to believe that a particular individual may alter or substitute the specimen to be provided.

(2) The collection site person shall ask the individual to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to tamper with or adulterate the individual's urine specimen. The collection site person shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments. The individual may retain his or her wallet.

(3) The individual shall be instructed to wash and dry his or her hands prior to urination.

(4) After washing hands, the individual shall remain in the presence of the collection site person and shall not use any water

fountain, faucet, soap dispenser, cleaning agent or any other material which could be used to adulterate the specimen.

(5) Toilet bluing agents shall be placed in toilet tanks wherever possible, so the water in the toilet bowl remains blue. There shall be no other source of water in the enclosure where urination occurs.

(6) The collection site person shall instruct the individual not to flush the toilet.

(7) The individual may provide his or her specimen in the privacy of a stall or otherwise partitioned area that allows for individual privacy.

(8) The collection site person shall note in writing in the chain of custody form any unusual behavior or appearance of the individual.

(9) In the event that a third party-designated collection site is not accessible and there is an immediate requirement for specimen collection, a public rest room may be used according to the following procedures:

(A) A collection site person of the same gender as the individual shall accompany the individual into the public rest room which shall be made secure during the collection procedure.

(B) If possible, a toilet bluing agent shall be placed in the bowl and any accessible toilet tank.

(C) The collection site person shall remain in the rest room, but outside the stall, until the specimen is collected.

(D) If no bluing agent is available, the collection site person shall instruct the individual not to flush the toilet until the specimen is delivered to the collection site person.

(E) After the collection site person has possession of the specimen, the individual will be instructed to flush the toilet and to participate with the collection site person in completing the chain of custody procedures.

(10) Upon receiving the specimen from the individual, the collection site person shall determine that it contains at least thirty

milliliters of urine. If there is less than thirty milliliters of urine in the bottle, the bottle and contents shall be discarded and another urine specimen shall be collected in a separate container. The individual may be allowed to drink a reasonable amount of water for this purpose. If the individual fails for any reason to provide at least thirty milliliters of urine, the collection site person shall contact the third party.

(11) After the specimen has been provided and submitted to the collection site person, the individual shall be allowed to wash his or her hands.

(12) Immediately after the specimen is collected, the collection site person shall measure the temperature of the specimen. The temperature measuring device used shall not contaminate the specimen with alcohol, drugs, or the metabolites of drugs. The time from urination to temperature measurement shall not exceed four minutes.

(13) The collection site person shall inspect the specimen for color and any other signs of contaminants. Any unusual findings shall be noted in the chain of custody form.

(14) The collection site person shall inspect the toilet, urinal or stall where the individual provided the urine specimen for any indication of specimen adulteration.

(15) If the temperature of a specimen is outside the range of 32.5 to 37.7 degrees Centigrade, or 90.5 to 99.8 degrees Fahrenheit, there is reason to believe that the individual may have altered or substituted the specimen, and another specimen may be collected under direct observation as an option of the third party, as described in subsection (a)(16) of this section. Both specimens shall be forwarded to the laboratory for testing. An individual shall be given the option to have his or her oral temperature taken to provide evidence to counter the reason to believe the individual may have altered or substituted the specimen caused by the specimen's temperature falling outside the prescribed

range.

(16) If there is reason to believe that the individual may have altered or substituted the specimen, based on subsections (a)(13) to (a)(15) of this section, another specimen may be collected with or without direct observation by a same gender collection site person, as an option of the third party. Both specimens shall be forwarded to the laboratory for testing.

(17) All specimens suspected of being adulterated shall be forwarded to the laboratory for testing.

(18) The collection site person and the individual shall be present at the same time during procedures outlined in subsections (a)(19) to (a)(22) of this section.

(19) The specimen shall be kept in view of both the individual being tested and the collection site person at all times prior to and while it is being sealed with the placement of a tamper-evident tape over the bottle cap and down the sides of the bottle.

(20) The collection site person shall place securely on the bottle an identification label which contains the date, the individual's specimen number, and any other identifying information provided or required by the third party.

(21) The individual shall initial the identification label on the specimen bottle for the purpose of certifying that it is the specimen collected from him or her.

(22) The collection site person shall enter in the permanent record book all information identifying the specimen. The collection site person shall sign the permanent record book next to the identifying information.

(23) The individual shall be asked to read and sign a statement in the permanent record book certifying that the specimen identified as having been collected from him or her is in fact that specimen he or she provided.

(24) The third party shall review and concur in advance with any decision that a specimen be collected under the direct observation of a same gender collection site person based on a reason to believe that the individual may

alter or substitute the specimen to be provided.

(25) The collection site person and the same gender observer, if applicable, shall complete the chain of custody form.

(26) If the specimen is not immediately prepared for shipment, it shall be placed in a tamperproof specimen bag, or shall be secured by another method, and placed in an appropriately safeguarded location during temporary storage.

(27) While any part of the above chain of custody procedures is being performed, it is essential that the urine specimen and custody documents be under the control of the involved collection site person. If the involved collection site person leaves his or her work station momentarily, the specimen and custody form shall be secured. After the collection site person returns to the work station, the custody process will continue. If the collection site person is leaving for an extended period of time, the specimen and documents shall either be packaged for mailing before he or she leaves the site, or be signed over to the custody of another collection site person prior to leaving the area.

(b) Collection site personnel shall arrange to have the collected specimens transported to the drug testing laboratory. The specimens shall be placed in containers designed to minimize the possibility of damage during shipment. The containers shall be securely sealed to eliminate the possibility of undetected tampering. On the tape sealing the container, the collection site person shall sign and enter the date specimens were sealed in the container for shipment. The collection site person shall ensure that the chain of custody documentation is attached to each container sealed for shipment to the drug testing laboratory.

(c) A copy of that part of the permanent record book containing information about the specimens shall be forwarded to the medical review officer.

(d) The permanent record book shall be the property of the third party, and the contents shall not be released to the testing laboratory.

(e) The collection site personnel shall keep

confidential all information contained in the permanent record book and the chain of custody forms.
[Eff JAN 23 1992] (Auth: HRS §§329B-4, 329B-5, 329B-6, 329B-8) (Imp: HRS §§329B-4, 329B-5, 329B-6)

§11-113-7 Blood specimen. (a) In addition to section 11-113-5 of this chapter, the collection of blood specimens shall include the following:

(1) Blood specimens may be drawn only by a physician, registered nurse, a person with a clinical laboratory personnel license, or a phlebotomist deemed qualified by the director of a clinical laboratory which is licensed by the state.

(2) The area of puncture shall be thoroughly cleansed and disinfected with an aqueous solution of non-volatile antiseptic. Alcohol shall not be used as a disinfectant if the blood specimen shall be tested for alcohol content.

(3) Blood shall be drawn with a sterile dry needle into a vacuum container; or a sterile dry needle and syringe and deposited in a clean dry container. The container shall be capped or stoppered and sealed.

(4) Each specimen must have the following information:
  (A) The individual's specimen number.
  (B) Date, time and place of blood specimen collection.
  (C) Name of the person drawing blood; and
  (D) Type and amount of preservative or anticoagulant, or both, used, if any.

[Eff JAN 23 1992] (Auth: HRS §§329B-4, 329B-8) (Imp: HRS §329B-4)

§11-113-8 Licensing of laboratories. (a) No laboratory in the state shall store or test specimens pursuant to this chapter without a current and valid substance abuse testing license from the department.

(b) A laboratory seeking licensure shall submit to the department a request in writing, for an application form.

(c) Each license issued pursuant to this chapter shall be issued to the owner of the laboratory and shall expire twenty-four months from the date of

issuance.

(d) A laboratory must meet all of the following provisions to qualify for licensure:

(1) The laboratory is located in this State.

(2) Laboratory personnel meet the qualifications specified in section 11-113-15.

(3) The laboratory facility performing substance abuse testing shall be secured.

(4) The laboratory shall use proper chain of custody procedures.

(5) The laboratory shall use screening or confirmatory testing procedures, or both, which are acceptable to the director.

(6) The laboratory shall have a quality assurance program which is acceptable to the director.

(7) The laboratory must be enrolled in a performance testing program which is acceptable to the director, at no cost to the department.

(e) As conditions to obtaining licensure, the laboratory must agree to and execute the following:

(1) Submit to the department all results of performance testing in a timely manner;

(2) Receive, test, and submit reports to the department on performance testing samples which may be supplied by the department, at no cost to the department.

(3) Notify the department within thirty days of any significant change in personnel, procedures, or operations which may affect the reliability and accuracy of testing and the accurate reporting of test results.

(4) Submit to onsite inspections by the director or the director's representative. A laboratory will be given at least twenty-four hours' oral or written notice, or both, before any inspection.

(f) The director may issue a license to any laboratory that meets the provisions of subsections (d) and (e) of this section and passes:

(1) An official laboratory inspection conducted by the department, and

(2) A performance test acceptable to the director.

(g) Testing of samples from Hawaii performed in another state may be performed only by laboratories currently licensed by that state to conduct substance

abuse testing, and whose standards are comparable to those contained in this chapter, and approved in writing by the director. The department shall not issue licenses to laboratories not physically located in this State.

(h) Under interim conditions, the director may issue a provisional license of limited duration to any laboratory in the state which meets the provisions of subsection (d) of this section.

(i) A license shall be forfeited prior to its expiration date if one or more of the following occurs:

(1) The owner sells or otherwise transfers the ownership of the laboratory.

(2) There is a change in the location of the laboratory or structural alteration without prior written approval by the department, which may affect adversely the quality of testing.

(3) The license holder surrenders the license to the department.

(4) The license holder fails to make full payment of the license fee.

(j) Upon any change in the ownership of a laboratory, the director may issue a provisional license, upon written application by the new owner pursuant to subsection (b) of this section;

(1) For a period not to exceed ninety days from the date of the change in the ownership of the laboratory,

(2) Upon written assurance by the new owner that the operation of the laboratory will continue to meet all provisions of subsection (d) of this section; and

(3) Upon onsite inspection by the director or the director's representative.

(k) The license shall specify the name and address of the laboratory, the name of the owner, types of specimens and tests which the licensee is allowed to perform, the specific substances of abuse for which the licensee is allowed to analyze, and the designated cutoff levels. The licensee must apply to the director of health for written approval of any changes or additions of tests of substances of abuse.

[Eff JAN 23 1992] (Auth: HRS §§329B-4, 329B-8) (Imp: HRS §329B-4)

§11-113-9 Revocation of laboratory license.
(a) The director shall revoke licensure of any laboratory licensed under this chapter if the director determines that the reliability and accuracy of substance abuse tests and the accurate reporting of test results by a licensed laboratory can no longer be ensured.

(b) The following factors shall be considered in determining whether revocation is necessary:

(1) Unsatisfactory performance in analyzing and reporting the results of drug tests;

(2) Unsatisfactory results in performance testing or laboratory inspections;

(3) Unsatisfactory participation in testing of specimens provided by the department;

(4) A material violation of any licensure provision in this chapter;

(5) Conviction for any criminal offense by key personnel of the laboratory in any incident directly related to the operations or maintenance of the laboratory, pursuant to chapter 831, Hawaii Revised Statutes;

(6) Any other cause which materially affects the ability of the laboratory to ensure the reliability and accuracy of drug tests and the accurate reporting of results, as determined by the director.

(c) The period and terms of revocation shall be determined by the director and shall depend on the facts and circumstances of the revocation and the need to ensure accurate and reliable substance abuse testing. [Eff JAN 23 1992] (Auth: HRS §§329B-4, 329B-8) (Imp: HRS §329B-4)

§11-113-10 Suspension of laboratory license.
(a) The director may immediately suspend a laboratory's license if:

(1) There is reason to believe that immediate action is necessary to protect the confidentiality of information concerning the tested individual; or

(2) There is reason to conclude that factors which significantly affect the achievement of reliable and accurate test results exist, as determined by the director.

(b) The period and terms of suspension shall be determined by the director and shall depend upon the

facts and circumstances of the suspension and the need to ensure reliable and accurate substance abuse testing. [Eff JAN 23 1992] (Auth: HRS §§329B-4, 329B-8) (Imp: HRS §329B-4)

§11-113-11 Opportunity for review of laboratory licensure. (a) When the director suspends or seeks to revoke licensure, the director shall immediately serve the laboratory with written notice of the suspension or proposed revocation by personal service, or by registered or certified mail, return receipt requested.

(b) The written notice shall state that the laboratory will be afforded an opportunity for a hearing of the suspension or proposed revocation if it so requests in writing within thirty days of the date of mailing or service of the notice. The review shall be conducted by one or more hearing officers designated by the director. [Eff JAN 23 1992] (Auth: HRS §§329B-4, 329B-8) (Imp: HRS §329B-4)

§11-113-12 Suspension effective date. A suspension shall be effective immediately. A proposed revocation shall be effective thirty days after written notice is given, or, if review is requested, upon the hearing officer's decision to uphold the proposed revocation. If the hearing officer does not uphold the suspension or proposed revocation, the suspension shall terminate immediately and any proposed revocation shall not take effect. [Eff JAN 23 1992] (Auth: HRS §§329B-4, 329B-8) (Imp: HRS §329B-4)

§11-113-13 Relicensing of laboratory. Following the termination or expiration of any suspension or revocation, a laboratory may apply for relicensing. Upon the submission of evidence satisfactory to the director that the laboratory is in compliance with this chapter, and any other conditions imposed as part of the suspension or revocation, the director may relicense the laboratory. [Eff JAN 23 1992] (Auth: HRS §§329B-4, 329B-8) (Imp: HRS §329B-4)

§11-113-14 Renewal of laboratory license. Laboratories seeking licensure renewal should request renewal in writing to the department not less than

three months prior to the expiration date of the license in force. [Eff JAN 23 1992] (Auth: HRS §§329B-4, 329B-8) (Imp: HRS §329B-4)

§11-113-15 Laboratory personnel. (a) The laboratory shall have a scientific director to assume overall professional responsibility for the laboratory's drug testing facility. This individual shall have the following minimum qualifications:

(1) A Ph.D. in one of the natural sciences such as toxicology, pharmacology, chemistry, or biological chemistry, or training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in toxicology, pharmacology, chemistry, or biological chemistry; and

(2) Appropriate experience in analytical forensic toxicology.

(b) The scientific director shall be responsible for the day-to-day management of the substance abuse testing laboratory, ensuring the competency of laboratory personnel by documenting their training, reviewing their work performance, and verifying their skills, for the continued maintenance of the procedure manual, maintaining quality assurance program, and assuring and documenting the validity, reliability, accuracy, precision and performance characteristics of each test and test system. The scientific director shall review all confirmatory test results for accuracy and reliability, and all chain of custody documents for specimens which have yielded positive test results.

(c) All persons who perform substance abuse testing shall meet one of the following requirements:

(1) Have a bachelor's degree from a college or university which is acceptable to the department, with a minimum of fifteen semester hours in college level chemistry courses;

(2) Have a license as clinical laboratory technologist or specialist in clinical chemistry from the department; or

(3) Have a minimum of four years of experience as an analyst in substance abuse testing, analytical chemistry, clinical chemistry, or biological chemistry.

[Eff JAN 23 1992] (Auth: HRS §§329B-4, 329B-8) (Imp: HRS §329B-4)

§11-113-16 Performance test requirement for licensure. (a) The performance testing program is part of:

(1) The initial evaluation of a laboratory seeking licensure; and

(2) The continuing assessment of laboratory performance necessary to maintain licensure.

(b) Successful participation in three consecutive cycles of testing shall be required before a laboratory is eligible to be considered for inspection and certification. These initial three cycles (and any required for recertification) can be compressed into a three month period (one per month). The performance tests shall include all drugs or metabolites of drugs, or alcohol for which the laboratory shall be licensed to analyze.

(c) After certification, laboratories shall be challenged every three months for a total of four cycles per year.

(d) The performance testing program must be acceptable to the director. [Eff JAN 23 1992] (Auth: HRS §§329B-4, 329B-8) (Imp: HRS §329B-4)

§11-113-17 Evaluation of performance testing.

(a) Initial application for licensure:

(1) An applicant laboratory shall not report any false positive results during performance testing for initial certification.

(2) An applicant laboratory shall maintain an overall grade level of eighty per cent for the three cycles of performance testing required for initial certification, as determined by the performance testing program or by the director when applicable.

(3) An applicant laboratory shall obtain at least eighty per cent of its quantitative values for confirmatory testing which are within plus or minus twenty per cent or plus or minus two standard deviations of the reference group mean (whichever is larger). Failure to achieve eighty per cent will result in disqualification.

(4) An applicant laboratory shall not obtain any

quantitative values that differ by more than fifty per cent from the calculated reference group mean. Any quantitative values that differ by more than fifty per cent will result in disqualification.

(5) For any individual substance of abuse or metabolite, an applicant laboratory shall successfully detect and quantitate in accordance with subsections (a)(2), (3), and (4) of this section at least fifty per cent of the total drug challenges. Failure to successfully quantitate at least fifty per cent of the challenges for any individual drug will result in disqualification.

(b) In order to remain licensed, laboratories must successfully complete four cycles of performance testing per year. Failure to maintain a grade of eighty per cent on any required performance test cycle may result in suspension or revocation of certification. The results of ongoing testing by licensed laboratories of performance test samples shall be sent by the scientific director to the department in a timely manner.

(c) A false positive result may be a basis for suspension. [Eff JAN 23 1992] (Auth: HRS §§329B-4, 329B-8) (Imp: HRS §329B-4)

§11-113-18 Laboratory procedures. (a) When a shipment of specimens is received, laboratory personnel shall inspect each package for evidence of possible tampering and compare information on specimen bottles within each package to the information on the accompanying chain of custody forms. Any direct evidence of tampering or discrepancies in the information on specimen bottles and the chain of custody forms attached to the shipment shall be immediately reported to the third party and shall be noted on the chain of custody form which shall accompany the specimens while they are in the laboratory's possession.

(b) Specimen bottles or containers will normally be retained within the laboratory's accession area until all analyses have been completed. Aliquots and the laboratory's chain of custody forms shall be used by laboratory personnel for conducting tests.

(c) Specimens that do not receive a test within seven days of arrival at the laboratory shall be placed

in secure refrigeration units at temperatures not exceeding ten degrees Centigrade. Emergency power equipment shall be available in case of prolonged power failure.

(d) When conducting either screening or confirmatory tests, each batch of specimens shall contain an appropriate number of standards for calibrating the instrumentation and a minimum of ten per cent of controls.

(e) No laboratory shall test for any substance which is not included in a written statement from the third party specifying the substances to be tested for.

(f) The screening test shall use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution, or any other method approved by the director. The cutoff levels for screening tests of urine specimens shall include, but not be limited to, the following:

(1)	Marijuana metabolites----------	100 ng/ml
(2)	Cocaine metabolites----------	300 ng/ml
(3)	Amphetamines----------	1000 ng/ml
(4)	Opiate metabolites----------	300 ng/ml
(5)	Phencyclidine and metabolites--	25 ng/ml
(6)	Barbiturates----------	300 ng/ml
(7)	Methaqualone----------	300 ng/ml
(8)	Benzodiazepines----------	300 ng/ml
(9)	Propoxyphene----------	300 ng/ml
(10)	Methadone----------	300 ng/ml

Cutoff levels in screening tests for other drugs and for using blood specimens shall be approved in writing by the director.

(g) All specimens which have presumptive positive test results shall be confirmed using gas chromatography/mass spectrometry techniques or any other technique deemed appropriate by the director. All confirmations shall be by quantitative analysis.

(h) The cutoff levels for confirmatory testing of urine specimens shall include, but not be limited to, the following:

(1)	Marijuana metabolites----------	15 ng/ml
(2)	Cocaine metabolites----------	150 ng/ml
(3)	Morphine----------	300 ng/ml
(4)	Codeine----------	300 ng/ml
(5)	Phencyclidine----------	25 ng/ml
(6)	Amphetamine----------	500 ng/ml
(7)	Methamphetamine----------	500 ng/ml
(8)	Barbiturates----------	200 ng/ml
(9)	Methaqualone----------	200 ng/ml

(10) Benzodiazepines---------- 200 ng/ml
(11) Propoxyphene---------- 200 ng/ml
(12) Methadone---------- 200 ng/ml
(13) Alcohol---------- 0.050 gram/100 ml

Cutoff levels in confirmatory testing for other drugs and for using blood specimens shall be approved in writing by the director.

(i) Before any test result is reported, it shall be reviewed and the test certified as accurate by the scientific director.

(j) The laboratory may transmit results and other information to the medical review officer by various electronic means in a manner designed to ensure confidentiality of the information. Results may not be provided verbally by telephone. The laboratory shall ensure the security of the data transmission.

(k) Unless otherwise instructed by the third party in writing, all records pertaining to a given specimen shall be retained by the laboratory for a minimum of two years.

(l) Unless otherwise authorized in writing by the third party, laboratories shall retain and place in properly secured long-term frozen storage the remainder of all positive specimens at minus ten degrees Centigrade or lower for a minimum of one year all specimens with a positive test result. Within this one year period the third party may request the laboratory to retain the specimen for an additional period of time, but if no such request is received the laboratory may discard the specimen after the end of one year, except that the laboratory shall be required to store any specimens under legal challenge for an indefinite period.

(m) A retest is not subject to a specific cutoff requirement but must provide data sufficient to confirm the presence of the drug or metabolite.

(n) Specimens which are negative for the requested substance abuse tests shall be discarded within one week after the reporting of the negative test result. [Eff JAN 23 1992] (Auth: HRS §§329B-4, 329B-6, 329B-8) (Imp: HRS §§329B-4, 329B-6)

§11-113-19 Quality assurance and quality control. (a) Laboratories shall have a quality assurance program which encompasses all aspects of the testing process including but not limited to specimen acquisition, chain of custody, security and reporting

of results, initial and confirmatory testing, and validation of analytical procedures. Quality assurance procedures shall be designed, implemented, and reviewed to monitor the conduct of each step of the process of testing.

(b) Each analytical run of specimens to be screened shall include:

(1) Specimens certified to contain no drugs;

(2) Specimens fortified with known standards; and

(3) Positive controls with the drug or metabolite at or near the cutoff.

(c) In addition, with each batch of specimens a sufficient number of standards shall be included to ensure and document the linearity of the assay method over time in the concentration area of the cutoff. After acceptable values are obtained for the known standards, those values will be used to calculate specimen data.

(d) Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall be documented.

(e) A minimum of ten per cent of all test specimens shall be quality control specimens. Laboratory quality control samples, prepared from spiked samples of determined concentration shall be included in the run and should appear as normal samples to laboratory analysts.

(f) Each analytical run of specimens to be confirmed shall include:

(1) Specimens certified to contain no drugs;

(2) Specimens fortified with known standards; and

(3) Positive controls with the drug or metabolite at or near the cutoff.

(g) The linearity and precision of the method shall be periodically documented. [Eff JAN 23 1992] (Auth: HRS §§329B-4, 329B-8) (Imp: HRS §329B-4)

§11-113-20 Medical review officer license. (a) For purposes of this chapter, no person shall serve as a medical review officer without possessing a current and valid medical review officer license from the director.

(b) All requests for licensure shall be in writing to the director.

(c) To qualify for licensure, a person must

present evidence of being a physician licensed to practice medicine in this or another state, and of knowledge of substance abuse disorders. After review of an applicant's professional experience in substance abuse, the director may issue a license to the applicant.

(d) The term of the license shall be twenty-four months from the date of issue.

(e) Any physician licensed pursuant to this section shall possess a current physician's license at all times.

(f) The director shall keep a current listing of all medical review officers practicing in the state. This listing may be sent to any third party in this state upon written request. [Eff JAN 23 1992] (Auth: HRS §§329B-2, 329B-4, 329B-5, 329B-8) (Imp: HRS §§329B-2, 329B-4, 329B-5)

§11-113-21 Revocation, suspension, or denial of medical review officer's license. (a) Any medical review officer license may be revoked or suspended by the director at any time, or may be denied, for any one or more of the following acts or conditions on the part of the holder of such license or the applicant therefor:

(1) Being habituated to the excessive use of drugs or alcohol; or being addicted to, dependent on, or an habitual user of a narcotic, barbiturate, amphetamine, hallucinogen, or other drug having similar effects;
(2) Practicing as a medical review officer while the ability to practice is impaired by alcohol, drugs, or mental instability;
(3) Procuring a license through fraud, misrepresentation, or deceit or knowingly permitting an unlicensed person to perform activities requiring a license;
(4) Professional misconduct, gross negligence, or manifest incapacity in functioning as a medical review officer;
(5) Revocation, suspension, or other disciplinary action by another state or federal agency of a license or certificate for reasons as provided in this section;
(6) Conviction, whether by nolo contendere or

otherwise, of a penal offense substantially related to the qualifications, functions, or duties of a physician;

(7) Violation of chapter 329, Hawaii Revised Statutes, Uniform Controlled Substance Act, or any administrative rule adopted thereunder;

(8) Failure to report to the director, in writing, any disciplinary decision issued against the licensee or the applicant in another jurisdiction within thirty days after the disciplinary decision is issued;

(9) Submitting to or filing with the director any notice, statement, or other document required under this chapter, which is false or untrue or contains any material misstatement or omission of fact.

(b) A medical review officer license may be revoked by the director if the director determines that revocation is necessary to ensure compliance with the provisions of this chapter. The period and terms of revocation shall be determined by the director and shall depend on the facts and circumstances of the revocation, and the need to ensure confidentiality of test results and other medical information.

(c) A medical review officer license may be immediately suspended by the director if evidence of one or more of the acts or conditions set forth in subsection (a) of this section exists, or upon conviction for any criminal offense committed in any incident directly related to the duties or functions of the medical review officer pursuant to chapter 831, Hawaii Revised Statutes. The period and terms of suspension shall be determined by the director and shall depend upon the facts and circumstances of the suspension. [Eff JAN 23 1992] (Auth: HRS §§329B-2, 329B-4, 329B-5, 329B-8) (Imp: HRS §§329B-2, 329B-4, 329B-5)

§11-113-22 Opportunity for review, medical review officer licensure. (a) When the director seeks to suspend or revoke the license of a medical review officer, the director shall immediately serve the medical review officer with written notice of the suspension or proposed revocation by personal service, or by registered or certified mail, return receipt requested. The notice shall state the following:

(1) The reasons for the suspension or proposed revocation;
(2) The terms of the suspension or proposed revocation; and
(3) The period of suspension or proposed revocation.

(b) The written notice shall state that the medical review officer will be afforded an opportunity for a hearing of the suspension or proposed revocation if the officer so requests in writing within thirty days of the date of mailing or service of the notice. The review shall be conducted by a hearing officer designated by the director and shall be based on written submissions by the medical review officer to the department.

(c) A suspension shall be effective immediately. A proposed revocation shall be effective thirty days after written notice is given, or if review is requested, upon the hearing officer's decision to uphold the suspension or proposed revocation. If the hearing officer decides not to uphold the suspension or proposed revocation, the suspension shall terminate immediately and any proposed revocation shall not take effect. [Eff JAN 23 1992] (Auth: HRS §§329B-5, 329B-8) (Imp: HRS §329B-5)

§11-113-23 Relicensing of medical review officer. Following the termination or expiration of any suspension or revocation, the individual may apply for relicensing. Upon the submission of evidence satisfactory to the director that the individual is in compliance with this chapter, and any other conditions imposed as part of the suspension or revocation, the director may relicense the individual. [Eff JAN 23 1992] (Auth: HRS §§329B-5, 329B-8) (Imp: HRS §329B-5)

§11-113-24 Renewal of medical review officer license. A medical review officer seeking licensure renewal should submit a written request for renewal to the department not less than two months prior to the effective expiration date of the current license. [Eff JAN 23 1992] (Auth: HRS §§329B-5, 329B-8) (Imp: HRS §329B-5)

§11-113-25 Responsibilities of medical review officer. (a) The medical review officer shall receive from the laboratory all positive test results and all chain of custody forms, and from the collection site, information about specimen-individual identifiers. If so desired by the third party, the medical review officer may also receive from the laboratory negative test results.

(b) For each positive test result, the medical review officer shall determine whether the result can be attributable to factors other than substance abuse. The medical review officer is responsible for the following actions:

(1) Consult with the laboratory officials if necessary.

(2) Request, if needed, a quantitative description of test results.

(3) Inform the tested individual of the test results.

(4) Offer to conduct a medical interview with the tested individual, but not necessarily face to face.

(5) Review the individual's medication disclosure form, medical history, or any other relevant biomedical factors which the individual has provided.

(6) Order a reanalysis of the original specimen by a laboratory if necessary.

(7) Consult with the third party, if necessary.

(c) The medical review officer shall verify a positive test result if the positive result is consistent with substance abuse based on the information obtained in subsection (b) of this section.

(d) The medical review officer shall report to the third party all verified positive test results. The individuals whose specimens yielded verified positive test results shall also be notified of the results by the medical review officer.

(e) The medical review officer shall designate as negative results all positive test results which cannot be verified.

(f) The medical review officer shall keep confidential all medication disclosure forms and all individuals' medical histories.

(g) The medical review officer shall retain records for three years unless notified by the third party that the test results are under legal challenge, in which case the records shall be retained for an

indefinite period of time. [Eff JAN 23 1992] (Auth: HRS §§329B-2, 329B-4, 329B-5, 329B-8) (Imp: HRS §§329B-2, 329B-4, 329B-5)

§11-113-26 Shipping of specimens. Specimens shall be placed in containers designed to minimize the possibility of damage during shipment to the substance abuse testing laboratory. The containers shall be securely sealed to eliminate the possibility of undetected tampering. On the tape sealing the container, the sender shall sign and enter the date of sealing in the container for shipment. The appropriate chain of custody documentation shall be attached to each container sealed for shipment to the substance abuse testing laboratory. [Eff JAN 23 1992] (Auth: HRS §§329B-4, 329B-8) (Imp: HRS §329B-4)

§11-113-27 Chain of custody. Procedures shall be instituted to account for the integrity of each specimen by tracking its handling and storage from the point of specimen collection to final disposition of the specimen. These procedures shall require that a chain of custody form be used from the time of collection to the receipt by the laboratory and that upon receipt by the laboratory an appropriate laboratory chain of custody form be used for the specimen or specimen aliquot within the laboratory. Chain of custody forms shall, at a minimum, include an entry documenting date and purpose each time a specimen or aliquot is handled or transferred and identifying every individual in the chain of custody. The chain of custody of the collecting site shall contain the "coded" identity of the individuals being tested. The laboratory chain of custody shall either use the coded identity of the collection site, or the accessioning number assigned by the laboratory, in which case laboratory chain of custody shall contain both the code and accessioning number. [Eff JAN 23 1992] (Auth: HRS §329B-4, 329B-8) (Imp: HRS §329B-4)

§11-113-28 Medication disclosure form.
(a) A medication disclosure form shall be presented to each individual to be tested before the individual provides a specimen.
(b) The medication disclosure form shall not contain the individual's name, but shall contain the

individual's specimen number, the date of specimen collection, the location of the collection site, the name of the collection site person, and the name of the testing laboratory.

(c) No information contained in the medication disclosure form may be revealed to the third party by the medical review officer. [Eff JAN 23 1992] (Auth: HRS §§329B-5, 329B-8) (Imp: HRS §329B-5)

§11-113-29 Reports. (a) The report from the laboratory to the medical review officer shall contain information on tests performed on specimens for drugs or the metabolites of drugs, including:

(1) The type of test conducted for each specimen.
(2) The cutoff level used to distinguish positive and negative specimens on both the initial and confirmatory tests.
(3) The name and address of the laboratory.
(4) Any additional information concerning the tests.

(b) In any arrangement between laboratories, which involves the transfer of specimens or portions of specimens, the analyzing laboratory shall be identified in all reports.

(c) No report to the third party shall contain any indication of presumptive positive test results or positive test results which cannot be verified.

(d) Procedures must be in place to ensure that the identity of an individual with a presumptive positive test result or an unverified positive test result, cannot be determined by the third party in any manner, including, but not limited to, the method of billing the third party and the time within which results are provided to the third party. [Eff JAN 23 1992] (Auth: HRS §§329B-4, 329B-5, 329B-6, 329B-8) (Imp: HRS §§329B-4, 329B-5, 329B-6)

§11-113-30 Transmittal of reports. The laboratory may transmit test results to the medical review officer by various electronic means in a manner designed to ensure confidentiality of the information. Results may not be provided verbally by telephone. The laboratory shall ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system. [Eff JAN 23 1992]

(Auth: HRS §§329B-4, 329B-5, 329B-6, 329B-8) (Imp: HRS §§329B-4, 329B-5, 329B-6)

§11-113-31 Licensing fees. (a) The following fees shall be paid to the department for a laboratory license:

	Type of License		
	Screening	Confirmatory	Both
Application	$100.00	$100.00	$100.00
Initial license	250.00	500.00	750.00
Renewal of license	100.00	100.00	100.00
Restoration of license	150.00	150.00	150.00

(b) Fees are non-refundable.

[Eff JAN 23 1992] (Auth: HRS §§329B-4, 329B-8) (Imp: HRS §329B-4)

§11-113-32 Confidentiality. (a) Any information concerning a substance abuse test pursuant to this chapter shall be strictly confidential. Such information shall not be released to anyone without the informed written consent of the individual tested and shall not be released or made public upon subpoena or any other method of discovery, except that information related to a positive test result of an individual shall be disclosed to the individual, the third party, or the decision maker in a lawsuit, grievance, or other proceeding initiated by or on behalf of the individual tested and arising from positive confirmatory test result.

(b) Any person who receives or comes into possession of any information protected under this chapter shall be subject to the same obligation of confidentiality as the party from whom the information was received. [Eff JAN 23 1992] (Auth: HRS §§329B-4, 329B-5, 329B-6, 329B-8) (Imp: HRS §§329B-4, 329B-5, 329B-6)

§11-113-33 Remedies. (a) Any person, agency, or entity that wilfully and knowingly violates any provision of this chapter shall be fined not less than $1,000 but not more than $10,000 for each violation as set by the department, plus reasonable court costs and attorney's fees as determined by the court, which

penalty and costs shall be paid to the aggrieved person. This subsection shall not be construed as limiting the right of any person or persons to recover actual damages.

(b) In addition to any other enforcement mechanism allowed by law, any person, agency, or entity that commits, or proposes to commit, any act in violation of this chapter may be enjoined therefrom by a court of competent jurisdiction. An action for injunctive relief under this subsection may be brought by any aggrieved person that will fairly and adequately represent the interests of the protected class. [Eff JAN 23 1992] (Auth: HRS §§329B-7, 329B-8) (Imp: HRS §329B-7)

§11-113-34 Severability clause. Should any section, paragraph, sentence, clause, phrase or application of this chapter be declared unconstitutional or invalid for any reason, the remainder of this chapter shall not be affected thereby. [Eff JAN 23 1992] (Auth: HRS §329B-8) (Imp: HRS §§329B-1, 329B-2, 329B-3, 329B-4, 329B-5, 329B-6, 329B-7)

DEPARTMENT OF HEALTH

Chapter 11-113, Hawaii Administrative Rules, on the Summary Page dated January 2, 1992, was adopted on January 2, 1992, following public hearings held on December 2, 3, 4 and 6, 1991, in Hilo, Honolulu, Kahului and Lihue, respectively, after public notice was given in the Hawaii Tribune-Herald, the Honolulu Advertiser, the Honolulu Star Bulletin, the Maui News, and the Garden Island on Friday, November 1, 1991.

The adoption of chapter 11-113 shall take effect ten days after filing with the Office of the Lieutenant Governor.

John C. Lewin, M.D., Director
Department of Health

APPROVED:

John Waihee
Governor
State of Hawaii

Dated: JAN 13 1992

APPROVED AS TO FORM:

Deputy Attorney General

JAN 13 1992
Filed